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ORIGINAL ARTICLE

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Patient injuries in operative rhinology during a ten-year period: Review of national patient insurance charts

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Objectives: To assess factors contributing to patient injuries in operative rhinology.

Design: Data of the accepted patient injury claims involving operative rhinology, between the years 2001 and 2011, were obtained from the Finnish Patient Insurance Centre registry. Two senior otolaryngologists analysed and evaluated the injury mechanisms.

Main outcome measures: Analysis and classification of factors contributing to patient injuries.

Results: During the ten-year study period, there were 67 patient injuries in operative rhinology, comprising 36% of all patient injuries in otorhinolaryngologic surgery. The majority (78%) of patients were treated in university or central hospitals and almost all (90%) by fully trained otolaryngology specialists. The factors contributing to the injuries were errors in surgical technique, like lesions to the orbit, skull base and meninges, and adjacent nerves, as well as mistakes with removable packings left in situ. Nearly half of the patients had undergone endoscopic sinus surgery. One patient died because of bleeding from the intracranial artery. Fourteen patients (21%) needed a re-operation due to the injury.

Conclusions: Patient injuries in rhinology were caused by typical complications of common operations performed by otorhinolaryngology specialists. The increased volume of endoscopic sinus surgery was evident also in patient injuries.

1 | INTRODUCTION

Patient injury is a tragedy to the patient and a burden to health care providers. Knowledge and awareness of potential errors as well as understanding of the underlying patterns of patient injuries have increased in recent years. Thorough and open research of previous errors offers a tool for efficient prevention and education. In 2005, Shah et al. emphasised that "every specialty must take responsibility for the study of human error within its own domain".[1]

1.1 | Adverse events in rhinology

Typical procedures in rhinology are performed in high volumes, are of short duration and do not cause immobility. All age groups are represented, and diseases are seldom associated with major co-morbidities. A high proportion of operations occur as outpatient or ambulatory surgeries. The type of anaesthesia varies. In Finland, the most basic nasal and sinonasal procedures, including endoscopic sinus surgery (ESS) with anterior ethmoidectomies and septoplasties, are carried out under local anaesthesia. Complications with major morbidity or mortality are relatively rare.

Procedures of the nose and paranasal sinuses are the largest subgroup (34.5%) of malpractice claims concerning operative otorhinolaryngology (ORL).[2] Rhinology accounts for about half of the cases and for about 70% of the indemnities paid on the entire ORL specialty by the malpractice insurers in the US.[2] Moreover, 35 cases (17.6% of ORL) of US malpractice lawsuits from the years 2001 to 2011 involved allegations of injury secondary to ESS.[3] These included errors in surgical technique, such as lesions of the orbit, skull base and adjacent nerves, in addition to problems with removable packing left in situ.[3]

The majority of patient injuries in rhinology are related to operative care. Critical anatomical structures adjacent to the nose and paranasal sinuses are close and vulnerable, which sets high demands for surgical technique.

In several studies, the overall major complication rate of ESS has been around 1%.[4,5] Even though the complication rate is quite low and much lower than at the beginning of the ESS era, the increasing operation volume increases the actual number of complications. The most commonly damaged structures are the cranial nerves, the orbit and the meninges.[4,6] In a nationwide study from the US, the complication rate of cerebrospinal fluid (CSF) leak was 0.2% and orbital injury 0.1%.[4] The consequences of ESS complications in 41 civil litigation malpractice cases in Boston were CSF leak (24%), brain damage (15%), diplopia (17%) and death (5%).[7] Conversely, 50% of the iatrogenic orbital complications are caused by ESS.[8]

1.2 | The Finnish healthcare and patient insurance system

The Finnish welfare state is characterised by a universal right to social welfare and healthcare services. Finland's social welfare and healthcare system is founded on government-subsidised municipal social welfare and healthcare services. Local municipal authorities operate health centres, which are the first point of contact for healthcare services. Hospital districts, formed by several municipalities, operate public hospitals. In addition to the public sector, many private enterprises and non-governmental organisations provide healthcare services.

According to the Patient Injuries Act (Potilasvahinkolaki 585/1986), all healthcare providers shall have patient insurance that compensates bodily damages to patients on a non-fault basis. The insurance covers for any personal injury caused to patients in the course of medical care. Compensation is, however, not paid for minor injuries. Insurance claims are addressed to the Finnish Patient Insurance Centre (PIC), which processes claims and pays compensation accordingly.[9]

Seven compensation criteria are listed in the Act: treatment injury, infection injury, accident injury, equipment-related injury, injury arising from damage to premises or treatment equipment, injury due to incorrect delivery of pharmaceuticals and unreasonable injury. A treatment injury is the most typical compensable injury. A compensable treatment injury is a bodily injury caused by an examination, treatment or other similar action performed on the patient, or the failure to do so. A pre-requisite for compensation is that an experienced medical professional could have performed a different procedure in the examination or treatment situation in question, thereby avoiding the injury. Consequently, a treatment injury may be, for example, a postoperative complication, such as a nerve injury or a delay in diagnosis, which could have been avoided by an experienced professional.

Finnish patient insurance system is not targeted to find the guilty ones but to provide fair compensation for the patient and tools for the healthcare system to better patient care in the future.

Keypoints

- Patient injuries in rhinology are strongly related to operative care.
- Almost half of the injuries are related to endoscopic surgery.
- Most injuries take place in common operations performed by fully trained specialists.

1.3 | Objectives

The aim of this study was to describe circumstances and identify errors contributing to patient injuries in operative rhinology.

2 | MATERIALS AND METHODS

2.1 | Ethical considerations

PIC approved the study protocol and design. Information regarding the identity of patient and healthcare providers has been excluded.

A retrospective review of the national patient insurance cases in Finland for a ten-year period was conducted. The study protocol and data search were approved by PIC. All patient injury claims within the ORL specialty, closed between 1 November 2001 and 31 October 2011, were sought from the PIC claim records database. The claims covered treatment given between the years 1998 and 2011.

The data from all operative patient injuries in ORL, including rhinology, were analysed to study their relation to the World Health Organization (WHO) Surgical Safety Checklist (SSC). These results were published in 2015.[10]

Age, gender, diagnosis and major co-morbidities of the patient in addition to information of the healthcare providers and institutions were recorded as background data. All medical records, experts' assessments and compensation decisions of the included claims were reviewed. Two ORL specialists evaluated the operation-related injuries in detail. Incidents and errors contributing to the injury were identified and classified. One or two noteworthy independent errors were defined for each patient. The structure of the classification used was modified from the classification presented for ORL by Shah et al.[11] It is based on the care flow process of the patient.

2.2 | Statistical analyses

For statistical processing, descriptive data were summarised using numbers and proportions (%). Statistical analyses were carried out with IBM SPSS software version 23 for Mac.

3 | RESULTS

During the ten-year study period, 233 claims were accepted as compensated patient injuries within the ORL specialty, 188 (81%)

TABLE 1 Characteristics of patients and healthcare providers in operative rhinology-related patient injuries

	N	%	Mean	min-max
Patient				
Age			46.9	11-76
Child, under 16 y	1	1.5		
Female	35	52.2		
Hospital				
University hospital	26	38.8		
Central hospital	26	38.8		
Local hospital	6	9.0		
Primary health care	3	4.5		
Private healthcare provider	6	9.0		
Physician				
ORL specialist	60	89.6		
ORL trainee	6	9.0		
Other	1	1.5		
Total	67	100.0		

ORL, otorhinolaryngology.
Number (N) and proportion (%).

of which were associated with operative care. A total of 67 patient injuries (36%) concerned operative rhinology. A typical patient was treated by a fully trained otolaryngologist in a high-volume centre (Table 1). Urgent operation resulted in patient injury for two patients (3%), and three patients (4%) suffered from a malignant disease.

Numbers of cases by year are presented in Figure 1. Of these, 32 cases (48%) were associated with ESS. An increase in the total number of patient injuries as well as ESS-related patient injuries is visible in 2004, 2005 and 2006. Numbers of operation types are presented in Table 2.

TABLE 2 Operations resulting in accepted patient injury claims in rhinology between 2001 and 2011

Operation type	N	%
Nasal skin tumour excision	2	3.0
Septoplasty	13	19.4
Septorhinoplasty	2	3.0
Sublabial rhinotomy	1	1.5
Cryogenic treatment of inferior turbinate	1	1.5
Open frontal sinus surgery	6	9.0
Transanthral sinus surgery	10	14.9
ESS	32	47.8
Total	67	100.0

ESS, endoscopic sinus surgery.
Number (N) and proportion (%).

Details of incidents and errors classified by care flow are presented in Table 3. In 31 cases (46%), two noteworthy independent incidents, such as iatrogenic trauma to the meninges and postoperative infection due to retained packing after surgery for the same patient, were detected. Manual error in performing surgery was identified as the primary incident in 44 cases (66%), of which incidental injuries to an adjacent nerve in 12 operations (18%) or other anatomical structures in 19 operations (28%) were the most common. There were no cases of wrong site surgery (WSS). Altogether seven patients (10%) suffered from problems related to retained foreign material (nasal or paranasal packing), resulting generally from insufficient documentation of materials left in situ.

Outcomes of the injuries for the patient varied from short-term harm to death. Altogether 14 patients (21%) needed a re-operation. Nerve injuries resulted often in permanent, but not severe, morbidity. One patient (2%) died due to an instrument invading the intracranial space, causing uncontrolled bleeding. Indemnities, related

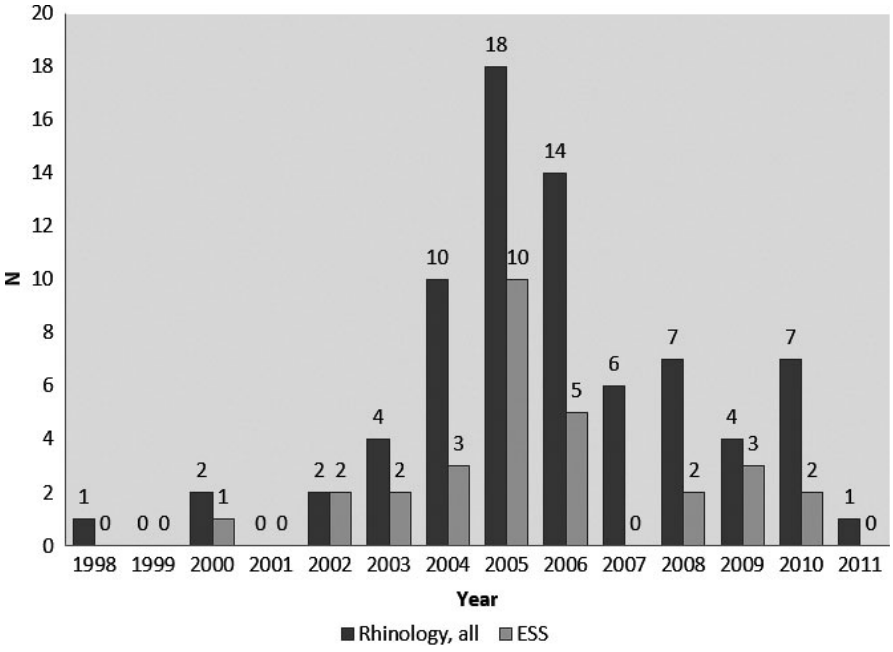

FIGURE 1 Accepted patient injury claims in operative rhinology between 2001 and 2011. N, number of operations; ESS, endoscopic sinus surgery

TABLE 3 Incidents and errors resulting in accepted patient injury claims in operative rhinology, classified on a care flow basis. In 31 claims (46%), two injury-contributing incidents occurred

Operative care	Incident 1 (N)	%	Incident 2 (N)	%
Preoperative judgement and surgical planning				
Incorrect/unnecessary procedure or technique	2	3.0	2	3.0
Insufficient patient information			2	3.0
Error in preoperative care			2	3.0
Operative unit				
No prophylactic antibiotic				
Problems in anaesthesia procedures				
Wrong site surgery				
Error in surgical technique				
Nerve lesion	12	17.9	2	3.0
Meningeal lesion	7	10.4		
Orbital injury	10	14.9		
Lacrimal injury	2	3.0		
Incomplete surgery	3	4.5		
Other technical error in performing surgery	6	9.0	7	10.4
Haemostatic problem	4	6.0	1	1.5
Retained gauze/instrument				
Equipment-related errors				
Insufficient charts or instructions			3	4.5
Other error in operation room				
Postoperative period				
Postoperative ward care				
Wrong/insufficient medication				
Infection	6	9.0	3	4.5
Haemorrhage	3	4.5		
Insufficient postoperative treatment/follow-up	3	4.5	4	6.0
Retained foreign body, eg nasal packing	5	7.5	2	3.0
Unintended result	4	6.0	3	4.5

Number (N) and proportion (%).

to operation-induced costs and harm, were paid in all accepted patient injury claims.

4 | DISCUSSION

4.1 | Synopsis of key findings

Most injuries were well-known complications of common procedures carried out by fully trained otolaryngologists in high-volume hospitals. Technical error in performing surgery was identified in two-thirds of injuries. Our study confirms that patient injuries in rhinology are strongly related to operative care.[5,11,12] Typically, injuries occur in routine procedures.

4.2 | Comparisons with other studies

Rhinology comprised 36% of all patient injury claims in ORL, and about half of the injuries were related to ESS. Accordingly, in the US, rhinologic procedures have been the largest subgroup (35%) of claims related to operative otolaryngology, and 70% of indemnity compensation in ORL has concerned rhinology.[2,5] Manual error in performing surgery was the cause for two-thirds of operation-related patient injuries. Most of these were injuries to adjacent structures. These findings are consistent with a previous claim record study.[13]

Errors occurred in common operations with experienced surgeons. This is in accordance with results exploring US surgical claims, including ORL.[13] Errors and complications occur even by the most experienced surgeons. The traditional view of surgical errors being linked to lack of surgical specialisation and low hospital volume is challenged.[13,14] Thus, the commonly recommended interventions, such as strict supervision of residents and restricting operations to high-volume hospitals, could eliminate only a minority of errors.[13]

In our series, the proportion of ESS-related patient injuries in operative rhinology was 48%, which is much less than the figure of 83% noted in a recent report from the US.[15] Our material reflects a transition phase from open to endoscopic procedures as almost one-quarter of cases represent open surgery (six cases of open frontal surgery and 10 cases of transanthral sinus surgery). Yet there were only three cases of malignant disease, meaning that benign diseases were treated quite aggressively according to today's standard. Patients are probably less ready to accept postoperative morbidity if the disease was not severe in the first place.

ESS-related errors included lesions to the orbit, skull base and adjacent nerves as well as problems with removable packing left in situ. Remarkable for ESS cases in our material was the insufficient documentation of materials left behind. Nowadays, the WHO SSC is used in Finland, and all materials should be recorded at the end of the operation, but this was not the case when the operations in the present study were performed. We have previously estimated that from all patient injury claims in ORL 9.6% are related to checklist items,and 4.8% could have been avoided if WHO SSC was used.[10] In the current material, the proportion would be even higher, as there were already seven cases (10%) of retained foreign material.

ESS became more popular in the early 2000s, and a peak in ESS-related patient injuries was evident around the year 2005. A learning curve for ESS explains to some extent both the increase and decrease of injuries. When we analysed patient charts, we noted that some ESS surgeons had lacked either or both the expertise and backup to perform a challenging ESS operation successfully. One surgeon was involved in four ESS-related patient injuries during quite a short period of time. Apart from that the claims were not concentrated on certain doctors. The decrease in ESS-related injuries

suggests that lessons have been learned, and the technique and patient selections are nowadays handled more successfully. Although the number of accepted patient injury claims concerning ESS seems high in 2005, the percentage is only 0.2%. As the number of ESS surgeries during the study period increased from 4198 in 1998 to 4429 in 2011, at least the more severe patient injuries in ESS are nowadays even more rare.[16]

None of the technical errors were explained due to the unavailability of preoperative CT in the OR. Image guidance may also have had an impact on the decrease of ESS-related complications after 2006. Due to the low complication rate, the influence of image guidance on complications is hard to measure statistically, but among endoscopists its use in advanced ESS is generally found to be beneficial.[17,18]

The proportion of septoplasties both in our material and in recent material from the US was as high as 19%.[15] Although septoplasties may be quite tricky, they are not as prone to defects of adjacent critical structures as the much more commonly performed endoscopic procedures. The high rate of dissatisfaction may reflect patients' unrealistic expectations. In two American studies, the type of malpractice in rhinology was non-indicated surgery or incomplete informed consent in 11 of 26 cases in one study and in 20 of 85 cases in the other study.[6,15] This emphasises the importance of conservative treatment, preoperative counselling and informed consent.

During the study period, a dramatic decline in the amount of septoplasties, open frontal sinus surgeries and transantral sinus surgeries took place. The change was 25% in septoplasties (from 2698 to 2015), 32% in open frontal sinus surgeries (from 154 to 105) and 71% in transantral sinus surgeries (from 643 to 187). During the whole study period, the proportion of accepted patient injury claims was 0.04% in septoplasties, 0.4% in open frontal sinus surgeries and 0.2% in transantral sinus surgeries.[16] In septoplasties, the yearly amount of patient injuries was quite stable, while in open frontal sinus surgeries and transantral sinus surgeries a decline in patient injury claims was noted. The yearly numbers were, however, too small for statistical comparison.

Implementation of the WHO SSC has promoted routine marking of the operation site.[18,19] Although marking of the operation site has not been routine among Finnish rhinologists, there were no WSS cases in our material. A survey sent to ORL specialists in North America revealed that 20% of responders did not mark the operation site at all and 30% relied on a review of the imaging as a check for the correct side for ESS.[20] The Sinus Surgery Checklist has recently been presented to prevent sinus surgery-specific errors.[21,22] It contains safety checks regarding the display of the radiograms, epinephrine labelling and documentation of materials left in situ. In a prospective observational study, the Sinus Surgery Checklist increased the performance of these safety tasks during the course of ESS.[22]

4.3 | Strengths and weaknesses of the study

Malpractice claim data and insurance records constitute a detailed source of information on patient injuries and their contributing or causal factors.[13,22] The PIC register used in the present study is nationwide, including all patient injury claims in Finland, therefore being highly representative. With retrospectively collected data, we are always dependent on information recorded in charts. In a few cases, the exact consequences of incidents remained unclear due to incomplete documenting.

The accepted malpractice or patient injury claims represent only a fraction of all errors and adverse events occurring in health care. The proportion of accepted and compensated patient injury claims in Finland was 26%, which is, perhaps surprisingly, close to US figures, where the respective rate for malpractice claims is 30%.[2,12] Even though the systems differ, the adverse effects and underlying mechanisms appear to be similar and comparable. Although all patients in Finland are insured by PIC, it is unlikely that all patients sustaining injuries during treatment submitted a compensation claim. Moreover, patients might be less eager to initiate a malpractice process due to the modest sum of the indemnity payment in Finland. Thus, the true volume of injuries is greater than that indicated by the number of claims handled by the PIC, with the true incidence of injuries being difficult/impossible to obtain.[23]

4.4 | Clinical applicability of the study

Carefully considered indications, thorough patient information, meticulous dissection and precise documentation of materials left in situ would cover most pitfalls in operations leading to accepted patient injuries in rhinology.

5 | CONCLUSION

Patient injuries in otolaryngology are strongly related to operative care and take place in common operations by experienced surgeons.

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CONFLICT OF INTEREST

The authors have no conflict of interest concerning the study.

AUTHORSHIP CONTRIBUTION

Karin Blomgren participated on the design of the study, read the files at the Patient Insurance Centre, participated on the analysis of the material, and was a co-writer of the manuscript. Päivi Helmiö and Leena-Maija Aaltonen participated on the design of the study, participated on the analysis of the material, and were co-writers of the manuscript. Lasse Lehtonen was a co-writer of the manuscript.

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